

We claim:

- 422/24
1. A process of sterilizing a medical device comprising:  
 5     subjecting said medical device to ultraviolet radiation whereby the  $D_{\text{value}}$  of Bacillus  
stearothermophilus (ATCC 7953) is at least  $3.9 \text{ mJ/cm}^2$  ultraviolet radiation (240-280 nm) to  
 the spore.
  - 10     2. The process of claim 1 wherein to provide a sterility assurance level of  $10^{-6}$ , said spore  
 is exposed to at least  $41 \text{ mJ/cm}^2$  of said UV radiation (240-280 nm) during said subjecting  
 step.
  - 15     3. The process of claim 1 wherein to provide a sterility assurance level of  $10^{-9}$ , said spore  
 is exposed to at least  $52 \text{ mJ/cm}^2$  of said UV radiation (240-280 nm) during said subjecting  
 step.
  - 20     4. The process of claim 1 wherein said radiation is delivered to said spore by at least one  
 pulsed radiation source.
  5. The process of claim 4 wherein each pulse delivers at least  $20 \text{ mJ/cm}^2$  UV radiation  
 (240-280nm) to said spore.
  - 25     6. The process of claim 1 wherein at least  $18 \text{ mJ/cm}^2$  UV radiation (240-280nm) is  
 delivered in less than 1 millisecond to said spore.
  7. The process of claim 1, wherein said radiation is delivered by more than 1 radiation  
 source.
  - 30     8. The process of claim 7, wherein said radiation sources are pulsed radiation sources  
 and said radiation sources pulse substantially simultaneously.
  9. The process of claim 8, wherein said radiation sources are flash lamps.

Sub B2 10. The process of claim 9, wherein said flash lamps each comprise a reflector and a lamp wherein the fluence of each of said flash lamps at the focal plane of said reflector is at least 45 mJ/cm<sup>2</sup> UV radiation (240-280 nm).

5 11. The process of claim 4, wherein said radiation is delivered by said pulsed radiation source in at most three pulses.

12. The process of claim 9, wherein said radiation is delivered by said flash lamps in at most three pulses.

10 Sub B3 13. The process of claim 1, wherein said radiation is produced by a laser.

14. The process of claim 1 wherein said medical device is in a container.

15 15. The process of claim 14, wherein said D<sub>value</sub> of Bacillus stearothermophilus (ATCC 7953) can be determined for a container by dividing 3.9 mJ/cm<sup>2</sup> by the transmissivity of said container exposed to said radiation source.

20 16. The process of claim 15, wherein the D<sub>value</sub> of B. stearothermophilus is at least 7.8 mJ/cm<sup>2</sup> ultraviolet radiation (240-280 nm) to the outside of said container, said container has a 50 % transmissivity to said ultraviolet radiation (240-280 nm).

17. The process of claim 16, wherein said medical device is a contact lens.

25 Sub B4 18. The process of claim 17, wherein said contact lens blocks at least 50 percent of the UV radiation (240-280 nm).

19. The process of claim 18, wherein said container further comprises an aqueous solution.

30 Sub B5 20. A process of sterilizing a medical device comprising:

subjecting said medical device to ultraviolet radiation wherein the minimum total energy density of said ultraviolet radiation (240-280 nm) to microorganisms on said medical device is at least 18 mJ/cm<sup>2</sup>.

- 5 21. The process of claim 20, wherein the minimum total energy density of said ultraviolet radiation (240-280 nm) to said microorganisms is at least 30 mJ/cm<sup>2</sup>.
22. The process of claim 20, wherein the minimum total energy density of said ultraviolet radiation (240-280 nm) to said microorganisms is at least 36 mJ/cm<sup>2</sup>.
- 10 23. The process of claim 20, wherein said minimum total energy density of said ultraviolet radiation (240-280 nm) is delivered to said microorganisms in less than 20 seconds.
- 15 24. The process of claim 21, wherein said minimum total energy density of said ultraviolet radiation (240-280 nm) is delivered to said microorganisms in less than 1 second.
- 20 25. The process of claim 21, wherein said minimum total energy density of said ultraviolet radiation (240-280 nm) is delivered to said microorganisms in less than 1 millisecond.
- 25 26. The process of claim 22, wherein said minimum total energy density of said ultraviolet radiation (240-280 nm) is delivered to said microorganisms in less than 1 millisecond.
27. The process of claim 20, wherein said radiation is provided by a pulsed radiation source which provides at least 20 mJ/cm<sup>2</sup> ultraviolet radiation (240-280 nm) per pulse to said microorganisms.
- 30 28. The process of claim 20, wherein prior to said subjecting step is the step of modifying radiation from a radiation source to eliminate wavelengths which would damage said medical device.

29. The process of claim 21, wherein said medical device is in a hermetically sealed container and wherein said minimum total energy density of said ultraviolet radiation (240-280 nm) which reaches said microorganisms, further reaches said contents of said container whereby the entire contents of said container and said medical device are sterilized.

5

30. The process of claim 29, wherein said sealed container further comprises a non-preserved aqueous solution.

*Sub B6*  
10 31. The process of claim 30 wherein said container is transmissive to at least 50 % of said ultraviolet radiation (240-280 nm).

32. The process of claim 31, further wherein said container is transmissive to at least 50 % of said radiation (240-280 nm) in substantially all directions.

*Sub B7*  
15 33. The process of claim 32 wherein said container comprises a lid and a bowl, wherein said lid and said bowl comprise thermoplastics and said lid and said bowl are transmissive to at least 50% of said radiation (240-280 nm) in substantially all directions.

*Sub B8*  
20 34. The process of claim 33 wherein said radiation is delivered by at least one flash lamp containing a rare gas as a luminous component.

35. The process of claim 34 wherein said medical device is a contact lens, and wherein said subjecting step follows the steps of:

- (a) forming a contact lens;
- (b) placing said contact lens in a container; and
- (c) moving said container into an apparatus comprising a radiation source;

and wherein said apparatus is light-tight during said subjecting step.

36. The process of claim 35, wherein the amount of radiation in the range of 240 to 280 nm delivered to the surfaces of said contact lens is between 18 mJ/cm<sup>2</sup> and 35 mJ/cm<sup>2</sup>.

Sub B9 37. The process of claim 35 wherein said medical device comprises a contact lens comprising UV-blocker which blocks greater than 50 % of the radiation between 240-280 nm.

5 38. The process of claim 37 wherein said radiation is delivered by at least two flash lamps which flash simultaneously.

Sub B10 39. The process of claim 37 wherein, the amount of said ultraviolet radiation (240 to 280 nm) delivered to said contact lens is between 18 mJ/cm<sup>2</sup> and 150 mJ/cm<sup>2</sup>.

10 40. The process of claim 39 wherein said flash lamps deliver at least 80 mJ/cm<sup>2</sup> total UV radiation (240-280nm) per flash to said container.

15 41. The process of claim 39 wherein said flash lamps deliver at least 100 mJ/cm<sup>2</sup> total UV radiation (240-280nm) per flash to said container.

20 42. An apparatus for delivering UV radiation to a medical device for sterilization comprising:

25 at least one radiation source and a reflector for each said radiation source wherein at least one said reflector directs radiation from each said radiation source to a treatment area, such that at least 3 J/cm<sup>2</sup> broad spectrum radiation of which at least 50 mJ/cm<sup>2</sup> of said radiation is UV radiation (240-280 nm) reaches said treatment area, said treatment area is located at the focal plane of said reflector, and further said treatment area is where said medical device is placed to receive the radiation.

30 43. The apparatus of said claim 42 wherein said radiation source is a flashlamp.

44. The apparatus of claim 43 further comprising a power supply which has a capacitance of 80 to 160 microFarad.

45. The apparatus of claim 44 further comprising a power supply which can generate a potential of 2500-6000 volts.

46. The apparatus of claim 45 wherein said radiation is discharged from said flash lamp in less than 1 millisecond.

47. The apparatus of claim 42 which has more than one radiation source wired in series.

48. The apparatus of claim 47 wherein said apparatus further comprises a second flashlamp.

49. The apparatus of claim 48 wherein said reflectors have enhanced reflection in the ultraviolet.

50. The apparatus of claim 49 wherein the reflector minimizes the non-ultraviolet radiation reaching the medical device.